K003729

JAN - 3 2001

510(k) Summary
(As required by 21 CFR 807.92)

A. Submitter Information

Submitter's Name:	St. Jude Medical, Daig Division
Address:	14901 DeVeau Place Minnetonka, Minnesota 55345-2126 U.S.A.
Telephone Number:	(952) 352-9716
Contact Person:	Angela Byland
Date Submission Prepared:	November 30, 2000

B. Device Information

Common or Usual Name:	Ultimum™ EV Hemostasis Introducer
Classification Name:	Catheter Introducer
Predicate Device:	Ultimum™ Hemostasis Introducer St. Jude Medical, Daig Division
Device Description:	The Ultimum™ EV (14F-20F) Hemostasis Introducers are introducers designed to provide easy access to the vascular system while providing convenient temporary closure of a standard indwelling introducer access site. The introducers include a sheath, hub, hemostasis valve, sideport for 3-way stopcock, and dilator. The introducers are provided sterile, and are intended for single-use only.
Intended Use:	The Ultimum™ EV Hemostasis Introducers are designed for the introduction of angiographic catheters, closed end catheters, balloon catheters and electrodes into a vessel where minimizing blood loss is essential.

C. Comparison of Required Technological Characteristics

All technological characteristics of the Ultimum™ EV Hemostasis Introducers are substantially equivalent to the predicate device including product design, packaging, sterilization, and labeling.

D. Support of the Substantial Equivalence

St. Jude Medical, Daig Division considers the Ultimum™ EV Hemostasis Introducers to be substantially equivalent to the predicate device, Ultimum™ Hemostasis Introducers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 3 2001

Ms. Angela Byland
St. Jude Medical
Daig Division
14901 DeVeau Place
Minnetonka, MN 55345

Re: K003729
Ultimum™ EV Hemostasis Introducer
Regulatory Class: II (two)
Product Code: 74 DYB
Dated: November 30, 2000
Received: December 4, 2000

Dear Ms. Byland:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003729

Device Name: Ultimum™ EV Hemostasis Introducer

Indications for Use:

The Ultimum™ EV Hemostasis Introducers are designed for the introduction of angiographic catheters, closed end catheters, balloon catheters and electrodes into a vessel where minimizing the blood loss is essential.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003729

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)